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Revel Michel

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EXAMINER

WANG, CHANG YU

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,294	Applicant(s) MICHEL ET AL.	
	Examiner Chang-Yu Wang	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/29/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7,8,54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 7, 8 and 54-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed 9/29/08 is acknowledged. Claims 2, 4, 6 and 9-53 are cancelled. Claims 1, 3, 5, 7 and 8 are amended. Claims 54-55 are newly added. Claims 1, 3, 5, 7, 8 and newly added claims 54-55 are pending in this application and under examination in this office action.
2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.
3. Applicant's arguments filed on 9/29/08 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Specification

4. The objection to the specification is withdrawn in response to Applicant's amendment to the title.

Claim Rejections/Objections Withdrawn

5. The rejection of claims 1-9 under 35 U.S.C. 112, first paragraph, because the specification does not enable the invention commensurate in scope with the claims is withdrawn in response to Applicant's amendment to the claims and cancellation of claims 2, 4, 6, and 9.

The rejection of claim 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to Applicant's amendment to the claim.

The rejection of claims 1-9 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in response to Applicant's amendment to the claims, Applicant's arguments and cancellation of claims 2, 4, 6, and 9.

The rejection of claims 1-9 under 35 U.S.C. 102 (b) as being anticipated by Nichols et al. (Exp. Cell Res. 1994. 215: 237-239 as in IDS) in response to Applicant's amendment to the claims, Applicant's arguments and cancellation of claims 2, 4, 6, and 9.

Claim Rejections/Objections Maintained

In view of the amendment filed on 9/29/08, the following rejections are maintained.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 7, 8 and 54-55 are rejected under 35 U.S.C. 102 (b) as being anticipated by WO01/88104 (Carpenter. published Nov 22, 2001) as evidenced by

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Baumann et al. (Physiol. Rev. 2001. 81:871-927). The rejection is maintained for the reasons made of record.

Claims 1, 3, 5, 7, 8 and 54-55 as amended are drawn to a method of generating O1⁺ and/or O4⁺ oligodendrocytes comprising growing neurosphere (NS) cells in a culture medium that promotes differentiation of NS cells into O1⁺ and/or O4⁺ oligodendrocytes, said culture medium comprising one or more gp130 activators selected from the group consisting of CNTF, oncostatin-M (OSM) or IL-6, IL6R/IL6 chimera and IL-11 thereby causing the NS cells to differentiate into O1⁺ and/or O4⁺ oligodendrocytes.

On p. 19 of the response, Applicant argues that Carpenter (WO01/188104) does not teach a culture medium to promote differentiation of NS cells into oligodendrocytes because Carpenter only teaches promoting differentiation into neuronal cells in general. Applicant argues that no example shows specific differentiation into oligodendrocytes because example 3 in the Carpenter reference is a cocktail of differentiation factors to cause A2B5-positive cells to mature into neural cells including oligodendrocytes, astrocytes and neurons and only 13% mature cells are GalC positive and only CNTF was used. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, the examiner asserts that Carpenter teaches the claimed method, which is a method of differentiating oligodendrocytes comprising growing primate pluripotent stem (pPS) cells including human embryonic stem cells in the presence of a gp130 activator including CNTF as recited in instant claim 1 (see p. 3; p. 6; p.8, lines 2-

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p. 11; p. 19, lines 10-35, examples, p. 20-23 examples 1-3, in particular). Carpenter teaches a method of differentiating cells re-suspended from cell suspensions from embryoid bodies, which are the same procedures to isolate the claimed NS cells that are derived from embryonic stem (ES) cells (see p. 19, lines 10-35, in particular). Applicant fails to demonstrate that the cultured NS cells derived from the suspension of embryoid bodies are different from the NS cells of Carpenter.

In addition, it is known in the art, the cultured neural precursor cells differentiate into a cell mixture encompassing different neural cells including neural progenitor cells, mature oligodendrocytes, astrocytes and neuronal cells. The instant specification fails to show that the claimed method only generates a pure homogenous O1+ and/or O4+ oligodendrocytes. In addition, the claimed method fails to limit the percentage of O1+ and/or O4+ oligodendrocytes. Furthermore, the culture medium in the claimed method encompasses more than one growth or differentiation factor, and the culture medium for culturing and differentiating NS cells in the Carpenter are identical to that of the instant, thus, the presence of CNTF would also be considered as the only factor as recited in instant claim 54. Moreover, the language "comprising" recited in instant claim 1 does not exclude other factors in the culture.

Thus, as previously made of record, as long as the cultured NS cells are cultured at the same conditions in the presence of CNTF (a gp130 activator) and the cultured cells differentiate into mature oligodendrocytes, which are O4+ and O1+ as evidenced by Baumann (see p. 875, 2nd col, 2nd -3rd paragraphs, in particular), the Carpenter's method anticipates the claimed method as recited in instant claims.

On p. 20 of the response, Applicant argues that Carpenter does not start with neurospheres (NS) cells as described by Zhang et al. Applicant further argues that claim 1 excludes the use of other differentiation agents. Applicant's arguments have been fully considered but they are not persuasive.

In response, Carpenter does teach NS cells because the NS cells of the instant claims are cultured at the same conditions as those of Carpenter, which are dissociated from cultured embryoid bodies. Carpenter teaches a method of differentiating cells re-suspended from cell suspensions from embryoid bodies, which are the same procedures to isolated the claimed neurosphere cells that are derived from embryonic stem (ES) cells (see p. 19, lines 10-35, in particular). Since the culture conditions of WO01/88104 are identical to those described in the instant specification on p. 11-14, the cells in the differentiation method of WO01/88104 are identical to the NS cells of the claimed method. Applicant fails to provide evidence to show that the cells of WO01/88104 are different from the claimed NS cells. Note that

"Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA1977)." See MPEP § 2112 [R-3]

If the product set forth in a product-by-process claim appears to be the same as, or an obvious variant of a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

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7. Claims 1, 3, 5, 7, 8 and 54-55 are rejected under 35 U.S.C. 102 (b) as being anticipated by US Patent No. 6562619 (Gearhart et al. issued on May 13, 2003, priority Mar 31, 1998) as evidenced by Baumann et al. (Physiol. Rev. 2001. 81:871-927). The rejection is maintained for the reasons made of record.

On p. 22 of the response, Applicant argues that Gearhart does not anticipate the claimed method because Gearhart does not teach differentiation of neurospheres and nor does disclose a culture medium to promote differentiation of oligodendrocytes. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, the examiner asserts that Gearhart does anticipate the claimed method. As previously made of record, Gearhart teaches a method of differentiating oligodendrocytes comprising growing embryonic stem (pPS) cells including mouse and human embryonic stem cells in the presence of a gp130 activator including IL-6 and IL-11 as recited in instant claims 1-9 (see col. 28, example 6; col. 30, claims 1-28, in particular). Gearhart also teaches embryoid bodies and NS cells derived from embryonic stem (ES) cells as the NS cells recited in instant claim 1 (see col. 29, lines 29-40; col.30, claim 9, In particular). The Gearhart' cells are re-suspended and passaged (col. 24-25, examples 1-2 and 6, in particular). Thus, the Gearhart's cells are identical to the NS cells in the claimed method. In addition, the culture medium in the Gearhart's method for differentiation contains IL6 or IL-11, which is a gp130 activator as recited in instant claims 1 (see col. 28, example 6; col. 30, claims 1-28, col 14, line 27- col. 15, line 4 in particular). Thus, Gearhart's method anticipates the claimed as recited in instant claims.

New Grounds of Rejection Necessitated by the Amendment

The following rejections are new grounds of rejections necessitated by the amendment filed on 9/29/08.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54 and 55 are indefinite because the claims recite “A method in accordance with claim 1”. The article “A” connotes that there is more than a single method encompassed within the base claim and since only a single method was set forth therein, it is unclear what, if any, additional methods are encompassed.

In addition, claim 54 recites that the gp130 activator is the only growth or differentiation factor present in the culture medium. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render

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a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 54 recites the broad recitation “culture medium”, which contain a lot of different factors for growth, and the claim also recites the gp130 activator is the only growth or differentiation factor present in the culture medium, which is the narrower statement of the range/limitation.

The recitation of “the gp130 activator is the only growth or differentiation factor present in the culture medium” is not consistent with the fact that the culture medium for growth or differentiation of oligodendrocytes containing other factors for growth and differentiation in the culture medium because the culture medium for NS cells described in the specification contains DMEM/F12, heparin, FGF-2, insulin, transferrin, putrescine, selenite, progesterone (p. 14 & p. 29) and the differentiation medium contains DMEM/F12 with insulin, transferrin, putrescine, selenite, progesterone (see p. 29).

Conclusion

9. NO CLAIM IS ALLOWED.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/

Chang-Yu Wang, Ph.D.

December 28, 2008

/Christine J Saoud/

Primary Examiner, Art Unit 1647